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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: James R. Lawter et al. Art Unit: 1617
Serial No.: 10/007,197 Examiner: Edward J. Webman
Filed: December 4, 2001 Customer No.: 21559
Patent No: 6,893,665
Issued: May 17, 2005
Title: FORMULATIONS FOR TREATING OR PREVENTING
MUCOSITIS

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APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

In response to the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) mailed with the Issue Notification on April 27, 2005 in connection with the above-captioned patent application, Applicants hereby request reconsideration of the patent term adjustment. Applicants submit that the current patent term adjustment should be 71 days.

The rules governing patent term adjustment due to examination delay are provided

for in 37 C.F.R. § 1.702, which states:

[T]he term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to: ... Respond to a reply under 35 U.S.C. 132 ... not later than four months after the date on which the reply was filed or the appeal was taken;

[T]he term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a).

37 C.F.R. § 1.703 further states:

The period of adjustment under 1.702(a) is the sum of the following periods:...[t]he number of days, if any, in the period beginning on the day after the date that is four months after the date the issue fee was paid and all outstanding requirements were satisfied and ending on the date a patent was issued.

With regard to reductions in patent term adjustment, 37 C.F.R. § 1.704(b) states:

With respect to the grounds for adjustment set forth in §§ 1.702(a) through (e), and in particular the ground of adjustment set forth in § 1.702(b), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-month period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed. The period, or shortened statutory period, for reply that is set in the Office action or notice has no effect on the three-month period set forth in this paragraph. ...

USPTO delay, as reflected in the PAIR system is as follows: The period between the response to the Non-Final Rejection, received on September 11, 2003 and the subsequent Non-Final Rejection, mailed on February 23, 2004 spans four months and 43 days. The period from November 12, 2004, the day the issue fee was recorded, to the

May 17, 2005 patent issue date spans four months and 66 days, as indicated on the PAIR system. The period from January 2, 2002, the day the application was completed, to the May 17, 2005 issue date spans 121 days, as indicated on the PAIR system. The calculated total days of USPTO, as indicated by the PAIR system, is 164 days.

Applicant delay, as reflected in the PAIR system, is as follows: The period between the Non-Final Rejection mailed on January 29, 2002 and the USPTO receipt of the corresponding response on July 29, 2002 spans three months and 91 days. The PAIR system also indicates that Applicant is assessed for a delay of 120 days for USPTO receipt of a miscellaneous incoming letter, which the PAIR system indicates is the Reply to the Notice of Allowance. Applicants respectfully disagree with the assessment of a 120 day Applicant delay as the Reply to the Notice of Allowance, mailed on August 11, 2004, was timely-filed.

In addition, if Applicant's Reply to the Notice of Allowance is deemed, for whatever reason, to be not timely filed, the fault for this was due to the actions of the USPTO, and not that of the applicant. On July 27, 2004, Applicants filed a Revocation and New Power of Attorney statement, transferring the power of attorney from Ratner Prestia to Clark & Elbing, the present attorney of record. Contained in this statement was the request that all correspondence regarding the application be sent to the Clark & Elbing address that is associated with customer number 21559. This document was received by the U.S. Patent and Trademark Office ("the U.S.P.T.O.") on July 30, 2004, as indicated by the U.S.P.T.O. stamp on the return postcard. However, the Notice of Allowance was

mailed to the previous attorney of record on August 11, 2004. Therefore, whatever delay that may be assessed regarding Applicant's Reply to the Notice of Allowance was due to USPTO error in mailing the Notice to the incorrect address and not to Applicant's failure to engage in reasonable efforts to conclude processing.

In view of the above facts, this application is currently entitled to 71 days of patent term adjustment under 37 C.F.R. § 1.703.

CONCLUSION

Applicants submit that the current patent term adjustment should be 71 days and request reconsideration of the patent term adjustment.

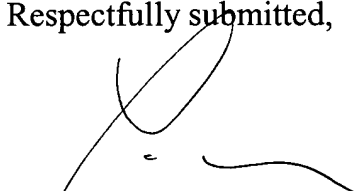
Enclosed is a check in the amount of \$200.00 for the fee set forth in 37 C.F.R. § 1.18(e).

If there are any additional charges or any credits, please apply them to Deposit

Account No. 03-2095.

Respectfully submitted,

Date: July 18, 2005



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